REMARKS

I. Status of the Application

Claims 1-23 were filed in the original application. In the Response to the Restriction Requirement mailed June 13, 2006, claims 1-12 were cancelled. In the Amendment and Response to the Office Action mailed May 3, 2007, claims 15-19, 22, and 23 were cancelled, and claims 13, 14, 20 and 21 were amended. In the Amendment and Response to Final Office Action of December 31, 2007 claims 13 and 14 were amended and claim 27 was added. In the present Amendment and Response to Office Action of April 11, 2008 claim 13 is amended and claim 28 is added. Applicants note that all amendments of claims are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),[1] and without waiving the right to prosecute the amended or cancelled claims (or similar claims) in the future.

In the present Amendment and Response to the Office Action mailed April 11, 2008, claim 28 is newly added. Support for newly added claim 28 may be found throughout the Specification at, for example, Example 6, page 78 and Example 7, page 79.

Thus, claims 13, 14, 20, 21 and 24-28 are currently pending in the application.

II. Record of the Interview Substance

Applicants provide herewith the following interview summary to be made of record with respect to the instant application. Applicants thank the Examiner for the helpful interview (hereinafter "Interview"). The substance of the interview was as follows:

Participants: Lisa Cook (Examiner), Kirk Hogan (Attorney) and David Casimir (Attorney).

1 65 Fed. Reg. 54603 (Sept. 8, 2000).

Date of Interview: October 10, 2008

Interview type: Telephone

Exhibit shown or demonstration conducted: None

Claims discussed: 13, 27

Art discussed: Danskine *et al.* (*Human Immunology*, 2002, Vol. 203, Supplement 1, pp S30), and Yang *et al.* (*Clinical and Experimental Immunology*, April 2002, Vol. 128, No. 1, pp 169-174).

Agreement with respect to claims discussed: Examiner suggested that the arguments and proposed amendments will be considered.

Identification of principal proposed amendments of a substantive nature discussed: Discussed amending claim 13 to specify that the subject is administered an anti-vimentin antibody, and that the pathogen is in the subject.

General thrust of the Applicants' principal arguments: That the Office Action at issue fails to establish the indefiniteness and non-enablement of claims 13 and 27 in view of Danskine and Yang.

General indication of any other pertinent matter discussed: Not applicable.

General results or outcome of the Interview: Examiner agreed to consider the Applicants' amendments and remarks.

III. Claim Rejections

In the Office Action of April 11, 2008 there are 2 rejections. The currently pending rejections are:

1. Claims 13 and 27 as well as dependent claims 14, 20-21, and 24-26 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention.

2. Claims 13-14, 20-21, and 24-26 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the enablement requirement

1.A. Claim 13 is Definite

In the Office Action of April 11, 2008 the Examiner notes:

"Claim 13 is directed to a method for reducing the risk of mortality in a subject. The method steps (a, i-iii) merely provides a pathogen, a subject having said pathogen, and an anti-vimentin antibody. In claim 13 step iii, the anti-vimentin antibody is administered to the subject. However, the relationship of the pathogen of *step i* and the remaining procedures of the method are ambiguous. Therefore, it is not clear that the pathogen is administer to the subject. This makes that claims vague and indefinite. It is not clear if the pathogen in present within the subject prior to antibody administration, if Applicant intends to administer a pathogen to the subject, or if the pathogen is a part of the claimed method. It is suggested that the relationship of the pathogen in the claimed method be clearly set forth in order to obviate this rejection. In other words the claims should clearly recite that the "*pathogen is administered to the subject*". (Office Action of April 11, 2008, page 3.)

Applicants respectfully disagree with the Examiner's assertion. However, in order to further their business interests, and while reserving the right to prosecute that original (or similar) claims in the future, Applicants have amended claim 13 to read "a) providing: i) a subject having said pathogen; and ii) an anti-vimentin antibody; and b) administering said anti-vimentin antibody to said subject having said pathogen under conditions such that said administering reduces the risk of mortality associated with said pathogen."

In view of the above, the Applicants request that this rejection be withdrawn.

1.B. Claim 27 is Definite

In the Office Action of April 11, 2008 the Examiner notes:

"Claim 27 is vague and indefinite in reciting that the pathogen has sepsis. It is not clear if it's Applicant intent to mean the subject has sepsis. As recited the metes and bounds of the claim can not be determined. Appropriate correction is requested." (Office Action of April 11, 2008, page 3.)

As discussed in the telephone interview with the Examiner of October 10, 2008, claim 27 reads: "The method of claim 13, wherein said subject having said pathogen has sepsis." Accordingly, Applicants note that it would be clear to an artisan of ordinary skill that it is the subject, and not the pathogen, that has sepsis.

In view of the above, the Applicants request that this rejection be withdrawn.

2. Claims 13-14, 20-21 and 24-26 are Enabled

In the Office Action of April 11, 2008 the Examiner notes:

"The ability to reasonably predict the capacity of a single bacterial immunogen to induce protective immunity from *in vitro* antibody reactivity studies is problematic. Unfortunately, the art is replete with instances where even well characterized antigens that induce an *in vitro* neutralizing antibody response fail to elicit *in vivo* protective immunity. See Blasi et al. (Clinical Pulmonary Medicine, 2002, 9/1, 6-12-Abstract) wherein *in vitro* data regarding C. pneumonia activity/treatment could not predict optimal dosing and length for in vivo activity/treatment." (Office Action of April 11, 2008, page 8.)

And:

"It has been set forth above that 1) the experimentation to generate an agent/drug/antibody/vaccine which provides treatment in a mammal/human against *a pathogen* would be great as 2) there are no immunological experiments provided to demonstrate that the claimed agents are capable of mounting an efficient immune response and, more importantly, there are no challenge experiments to demonstrate that a person immunized with any one of the claimed anti-vimentin antibody agents would be protected from *a pathogen*." (Office Action of April 11, 2008, page 8.)

As discussed in the telephone interview with the Examiner of October 10, 2008, claim 13 does not recite administration of a bacterial immunogen, administration of an antigen, induction of a neutralizing antibody response, or administration of a vaccine. Accordingly, immunological experiments that demonstrate "an efficient immune response" are not relevant to the methods of the present claims. In view of the above, the Applicants request that this rejection be withdrawn.

In the Office Action of April 11, 2008 the Examiner notes:

"The prior art teaches that the presence of anti vimentin antibodies is linked to detrimental results in patients. See the abstract to Danskine et al. (Human Immunology, 2002, Vol. 63, Supplement 1, pp S30) wherein anti-vimentin antibodies were correlated with acute and chronic cardiac transplantation rejection. See also the reference to Yang et al. (Clinical and Experimental Immunology, April 2002, Vol 128, No. 1, pp 169-174) were high levels of antivimentin antibodies are linked to IPF (idiopathic pulmonary fibrosis), NSIP (non-specific interstitial pneumonia), systemic lupus erythematosus, progressive vascular sclerosis and RA. Thus from the prior art teaching the administration of anti-vimentin antibodies to a subject would appear to induce diseases and/or disorders linked to bacterial pathogens. This is contrary to the instant invention which is directed to reduced risk of mortality. See abstract and page 128 – Discussion." (Office Action of April 11, 2008, page 5.)

Applicants respectfully disagree with the Examiner's assertion. However, in order to further their business interests, and while reserving the right to prosecute that original (or similar) claims in the future, Applicants have amended claim 13 to read "a) providing: i) a subject having said pathogen; and ii) an anti-vimentin antibody; and b) administering said anti-vimentin antibody to said subject having said pathogen under conditions such that said administering reduces the risk of mortality associated with said pathogen." Applicants note that the anti-vimentin antibodies of claim 13 reduce the risk of mortality associated with a pathogen. Claim 13 does not address mortality from diseases and disorders that are not associated with a pathogen. Contrary to the Examiner's interpretation of Danskine and Yang, none of the diseases and disorders cited in the rejection of April 11, 2008 (*i.e.,* IPF (idiopathic pulmonary fibrosis), NSIP (non-specific interstitial pneumonia), systemic lupus erythematosus, progressive vascular sclerosis and RA) are "linked to bacterial pathogens". Nor do Danskine and Yang demonstrate that the diseases and disorders cited in the rejection of April 11, 2008 are caused by administration of an anti-vimentin antibody. In view of the above, the Applicants request that this rejection be withdrawn.

Moreover, even if the references were properly cited in a 112 rejection (Applicants believe they were not), neither Danskine nor Yang teach or suggest administration of an anti-vimentin antibody. Danskines's antibodies arise from "de novo production" after cardiac transplantation (Danskine, first paragraph). Yang's antibodies "are formed in some patients with IPF, idiopathic NSIP and NSIP associated with polymyositis/dermatomyositis" (Yang, page 173). Thus, none of the cited references are on point as the detrimental effect observed was related to specific patient types under specific conditions. Nor can the cited references be reasonably extended to make the point raised by the rejection. These facts were included in the Amendment and Response to Final Office Action of December 31, 2007, and were not considered in the Office Action of April 11, 2008. In view of the above, the Applicants request that this rejection be withdrawn.

In turn, even if there were side effects attendant to administration of anti-vimentin antibody (Applicants believe that no valid evidence has been presented in support of such an argument), the presence or absence of side effects would not support a lack of

enablement. The rejection provides no evidence that administration of anti-vimentin antibody to reduce mortality in pathogen-infected subjects has deleterious side effects, or that such methods would find no use even if there were deleterious side effects. To the contrary, the Specification shows a clear benefit. Thus, the evidence of record does not support the rejection. These facts were included in the Amendment and Response to Final Office Action of December 31, 2007, and were not considered in the Office Action of April 11, 2008. In view of the above, the Applicants request that this rejection be withdrawn.

In the Office Action of April 11, 2008 the Examiner notes:

> "Further, the specification does not set forth any in vivo data showing the protective ability of anti-vimentin antibody administration to a subject other than vimentin knock out mice with goat anti-vimentin serum." (Office Action of April 11, 2008, page 6.)

Applicants respectfully disagree with the Examiner's assertion. For example, the experimental animals of Example 7, page 79 are not vimentin knock-out mice. Example 7 demonstrates that anti-vimentin antibodies protect subjects from fatal intraperitoneal infection with lethal doses of *E. coli* in a well-characterized *in vivo* model of bacterial sepsis. Accordingly, the Specification provides explicit support for the methods of reducing mortality in a subject having a pathogen of the presently claimed invention *i.e.*, administration of anti-vimentin antibodies. Morevoer, one skilled in the art finds abundant details for the methods of use of the anti-vimentin antibodies of the presently claimed invention throughout the Specification at, for example, "**II. Secretory Vimentin Antibodies**" line 1, page 37 to line 5 page 40, and "**V. Secretory Vimentin Pharmaceutical Compositions**" line 16, page 63 to line 2, page 68. These facts were included in the Amendment and Response to Final Office Action of December 31, 2007, and were not considered in the Office Action of April 11, 2008. In view of the above, the Applicants request that this rejection be withdrawn.

In the Final Office Action of December 31, 2007 the Examiner argues:

"The prior art teaches that species specific antibodies against vimentin have different reactivity. See abstract to Bohn et al. (Experimental Cell Research, Vol 201., No. 1, July, 1992, pages 1-7). The prior art also teaches that in vitro results can not predict in vivo antibody responses. See Pallini et al. (Journal of Neuro-Oncology, Vol. 49, 2000, pages 9-17)." (Office Action of April 11, 2008, page 6.)

The Applicants respectfully disagree with the relevance of the Examiner's assertions. As the Examiner acknowledges, Experimental Examples 6 and 7 provide explicit and clear cut *in vivo* data. Example 6 shows that a decrement in vimentin prolongs life after injections of lethal doses of *E. coli*. Example 7 shows that specific intervention with anti-vimentin antibody reduces mortality after injections of lethal doses of *E. coli*. To the contrary, Pallini describes the behavior of brain cancer cells *in vitro*. Pallini does not teach, suggest, or even consider *in vitro* or *in vivo* consequences of anti-vimentin antibody administration on a pathogen, or on a subject having a pathogen. Bohn describes anti-vimentin antibody reaction patterns on vertebrate cells. Bohn does not teach, suggest, or even consider *in vitro* or *in vivo* consequences of anti-vimentin antibody administration on a pathogen, or on a subject having a pathogen. Accordingly, nothing in Pallini or Bohn is relevant to whether or not one skilled in the art would be enabled to make and/or use the inventions of the present claims. These facts were included in the Amendment and Response to Final Office Action of December 31, 2007, and were not considered in the Office Action of April 11, 2008. In view of the above, the Applicants request that this rejection be withdrawn.

In the Final Office Action of April 11, 2008 the Examiner argues:

"Devoid of results supporting in vivo killing of a other pathogen/sepsis by other species of anti-vimentin antibodies, the skilled artisan would not be able to predict the outcome of the administration of the claimed anti-vimentin antibodies activity, i.e. would not be able to accurately predict if anti-vimentin antibodies agents would be useful in the claimed purpose." (Office Action of April 11, 2008, page 6.)

The Applicants respectfully disagree with the Examiner's assertion. For example, "in vivo killing of a other pathogen/sepsis" is not a limitation of the claims. However, in order to further the business interests of the Applicants, and while reserving the right to prosecute that original (or similar) claims in the future, in the present Amendment and Response to the Final Office Action of December 31, 2007, the Applicants have amended claim 13 to read "administering said anti-vimentin antibody to said subject having said pathogen under conditions such that said administering reduces the risk of mortality associated with said pathogen." In view of the above, the Applicants request that this rejection be withdrawn.

CONCLUSION

All grounds of rejection of the Final Office Action dated April 11, 2008 have been addressed, and reconsideration of the application is respectfully requested. It is respectfully submitted that the Applicant's claims should be passed into allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

Dated: October 13, 2008

/David A. Casimir/

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